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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/066,810 | 02/04/2002 | Eva-Marie Mandelkow | 28384/38187 | 6127 |

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EXAMINER

CHERNYSHEV, OLGA N

ART UNIT PAPER NUMBER

1646

DATE MAILED: 02/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|---------------------------------------|---|--|
| Office Action Summary | Application No. 10/066,810 | Applicant(s) MANDELKOW ET AL. | |
| | Examiner Olga N. Chernyshev | Art Unit 1646 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 January 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33-66 is/are pending in the application.
- 4a) Of the above claim(s) 41-66 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 September 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Claims 33 and 39 have been amended as requested in the amendment filed on January 06, 2005. Claims 33-66 are pending in the instant application.

Claims 41-66 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper filed on October 01, 2003.

Claims 33-40, in so far as they encompass an antibody that binds phosphorylated tau epitope comprising phosphorylated residue 262 in SEQ ID NO: 1, are under examination in the instant office action.

2. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

4. Applicant's arguments filed on January 06, 2005 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Drawings

5. The amendment to the Drawings filed on September 29, 2004 is considered non-compliant because it has failed to meet the requirements of 37 CFR 1.121, as amended on June 30, 2003 (see *68 Fed. Reg. 38611*, Jun. 30, 2003) with respect to identification of amended

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drawing sheets. Specifically, replacement drawing sheets must be identified in the top margin as “Replacement Sheet” and new drawing sheet must be identified in the top margin as “New Sheet”. Appropriate correction is required.

Specification

6. The amendment to the abstract filed on September 29, 2004 is considered non-compliant because it has failed to meet the requirements of 37 CFR 1.121, as amended on June 30, 2003 (see *68 Fed. Reg. 38611*, Jun. 30, 2003). Specifically, any new, or replacement, abstract must be submitted on a separate sheet (37 CFR 1.72). Appropriate correction is required.

7. It is noted that amendment to the specification, as filed on September 29, 2004, includes references to paragraphs numbered as sections. However, the instant specification, as filed on February 04, is presented as a plain text. Clarification of the amendment is required.

8. In response to Applicant’s concern as not being able to locate the unidentified sequence on page 59 (section I on page 27 of the Response), Applicant’s attention is directed to page 59, third paragraph, second line, sequence “KSPV”, of the instant specification, as originally filed. Appropriate correction to comply with the sequence rules as explained in section 1 of the office action mailed on March 26, 2004 is required.

Claim Rejections - 35 USC § 112

9. Claims 33-40, as amended, stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement for the reasons of record in section 6 of Paper mailed on March 26, 2004. The claim(s) contains subject matter which was not described in the

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specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention.

Applicant traverses the rejection on the premises that because the skill in the field of the invention is high, “Applicants submit that undue experimentation would not be required to use Applicant’s invention as presently claimed” and refers to holdings in *Hybritech v. Monoclonal Antibodies* (bottom at page 28 of the Response). Applicant’s arguments have been fully considered but are not deemed to be persuasive for the following reasons.

There appears to be no disagreement that a specification does not have to teach what is well known in the art and further, that production of antibodies in general, is extensively described in textbooks and laboratory manuals. However, the issue at hand remains that Applicant claims very specific antibodies, such as an antibody that binds a tau epitope comprising a serine residue 262 in SEQ ID NO: 1 only when the serine residue is phosphorylated. As fully explained in the previous office action of record, the instant specification, as filed, fails to present any guidance on how to produce an antibody that binds to phosphorylated Serine at position 262 and does not bind native or dephosphorylated Serine at residue 262. In the instant case, one skilled in the art cannot rely on prior art for guidance on how to produce such unique antibody and, since the instant disclosure provides no protocol or working examples, the skilled artisan would have to perform a significant amount of undue experimentation in order to practice Applicant’s invention, as currently claimed.

Therefore, for reasons of record in the previous office action and reasons explained above, the instant rejection is maintained.

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10. Claim 40 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record in section 9 of Paper mailed on March 26, 2004.

Double Patenting

11. Double patenting warning regarding claims 33 and 34-35 is maintained for reasons of record in section 11 of Paper mailed on March 26, 2004.

Conclusion

12. No claim is allowed.

13. This application contains claims 41-66 drawn to an invention nonelected with traverse in Paper filed on October 01, 2003. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C. Caputa can be reached on (571) 272-0829. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 872-9306. If this number is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (571) 273-0870. Official papers should NOT be faxed to (571) 273-0870.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Olga N. Chernyshev, Ph.D.
Primary Examiner
Art Unit 1646

February 15, 2005